

Memo

To: Gary Harkcom, Acting Chairman of the Board of Patent Appeals and Interferences

Stephen G. Kunin

From: Stephen G. Kunin, Deputy Commissioner for Patent Examination Policy

Date: February 27, 2004

Re: Request for Reconsideration by the BPAI for 09/051,827

The Application

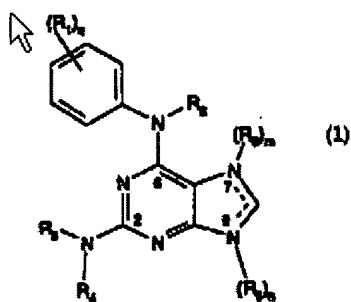
Application 09/051,827, filed 1 May 1998, is a 371 of PCT/EP96/04573, filed 22 October 1996. Examiner Mark Berch, GAU 1624, examined the application.

The Claims

The claims are directed to compounds that are 2-amino-6-anilino purine derivatives, process for preparation of the compounds, a pharmaceutical composition and a method of treating tumors using the compounds.

Sample claims:

Claim 2. A compound of the formula I



in which q is 1-5,

R₁ is halogen; lower alkyl; hydroxyl; lower alkanolxy; lower alkoxy which is substituted or unsubstituted by hydroxyl, lower alkoxy or carboxyl...

R₂ is hydrogen, carbamoyl or N-lower alkyl-carbamoyl,

m and n are each 0 or 1, where m is 0 if n is 1 and m is 1 if n is 0,

dashed lines represent a single bond which is located between N-7 and C-8 if m is 0 and located between C-8 and N-9 if m is 1,

R₃ is lower alkyl or phenyl which are unsubstituted or in each case substituted by hydroxyl, lower alkoxy, amino, lower alkylamino or N,N-di-lower alkylamino and

a) R₄ is hydrogen, amino, phenylamino, lower alkylamino, hydroxyl, phenoxy, lower alkoxy;... an aliphatic hydrocarbon radical having not more than 29 C atoms, which is substituted by ...mercapto, lower alkylthio, thiocarbamoyl, thioureido, N-lower alkyl-thioureido, N-phenyl-thioureido, guanidine, N-lower alkyl-guanadino,...hydroxyl,...

R₅ independently of R₄, is as defined above for R₄, with the exception of hydrogen and an aliphatic hydrocarbon radical having not more than 29C atoms, which is substituted by hydroxyl, or

b) R₄ and R₅ together are 1,2-ethylene, propane-1,3-diyl, butane-1,4-diyl, pentane-1,5-diyl, 3-(3-amino-propionyl)-3-aza-pentane-1,5-diyl, 1-aminomethyl-butane-1,4-diyl, 1-hydroxy-methyl-butane-1,4-diyl, 3-(2-amino-ethyl)-pentane-1,5-diyl, 3-aza-pentane-1,5-diyl or 3-(2-amino-ethyl)3-aza-pentane-1,5-diyl, or a salt thereof.

Claim 3. A compound of the formula I according to Claim 2, in which

q is 1-3 and R₄ is hydrogen,

or a salt thereof.

The rejection

Applicant appealed the rejection of claims 2, 3, 14, 16, and 18-19 under 35 U.S.C.112, 1st paragraph, as containing subject matter which was not described in the specification, specifically the use of "mercapto" in the definition of R₄ as set forth in claim 2, rather than the "thio" originally employed.

The examiner's position, as explained on page 4 of the Examiner's Answer (Paper No. 16) is that:

The term "thio" is not a name for a substituent, or a class of substituents, but a generic term...indicating only the presence of sulfur in some form.

There could have been intended three possible choices:

1. Thioxo, doubly bonded sulfur (=S).
2. Mercapto (-SH).
3. It can also denote replacement of some other atom (normally, oxygen or carbon) by S, as in "thioalkoxy", where O in alkyl-O- is replaced by S to give alkyl-S-. Or perhaps some term which began with "thio", like "thiophene", was intended.

The decision

The board of appeals affirmed the rejection of claims 2, 14, 16, 18 and 19 under 35 U.S.C. 112, first paragraph written description requirement, however they reversed the rejection of claim 3 under the same grounds, see page 7 of the decision. On page 8, the decision states "Claim 3, however, stands on different footing. This follows because, in claim 3, R₄ is hydrogen. This claim does not include the recitation of R₄ as 'an aliphatic hydrocarbon radical having not more than 29 C atoms, which is substituted by...mercapto.' In other words, claim 3 does not include the very recitation which gives rise to the examiner's rejection under 35 U.S.C. § 112, first paragraph (written description requirement). The examiner's position to the contrary, notwithstanding, the written description issue does not apply 'equally' to claims 2, 3, 14, 16, 18, and 19 (Paper No.16, section 7)."

Issue

The reversal by the BPAI of the rejection of claim 3 for new matter appears to be based on an incomplete analysis of the claims as detailed below:

The Board reversed with regard to Claim 3, pointing out, correctly, that claim 3 says, "R₄ = H". The problem is, the Board overlooked R₅, whose definition is linked to R₄ in

independent claim 2. The independent claim says, “R₅ independently of R₄, is as defined above for R₄, with the exception of hydrogen and an aliphatic hydrocarbon radical having not more than 29C atoms, which is substituted by hydroxyl...”. Thus, claim 3 limited R₄, but **did not limit R₅**, since the definitions are independent (they would have to be, since claim 3 requires R₄ as H, which R₅ isn’t permitted to be). In claim 3, R₅ can be an aliphatic hydrocarbon radical having not more than 29C atoms which is substituted by mercapto. Thus this claim has the same new matter problem regarding mercapto as independent claim 2. Had this detail not been overlooked by the Board, the rejection of claim 3 would also have been affirmed.

Reason for BPAI to reconsider

The Board clearly stated in their decision that “For reasons succinctly stated by the examiner (Paper No.16, page 4) the applicant’s original disclosure of ‘thio’ does not provide adequate support for the newly introduced term ‘mercapto’.” Decision at 7. By completing the analysis of claim 3, taking into account the definition of R₅, the Board should clearly see that the reversal of the new matter rejection of claim 3 was factually incorrect. Note that an effort by the examiner to resolve the issue with appellant was unsuccessful.

For these reasons, reconsideration of the Board’s decision is respectfully requested.